

REMARKS

Claims 1-10 are all of the claims pending in the application; each of the claims has been rejected.

Claim 1 has been amended to provide the full name of each species of *Eimeria* strain recited in the claim. The claims have been amended to place them more fully in U.S. format.

No new subject matter has been added. Entry of the amendment is respectfully solicited.

I. Formal Matters

Applicants respectfully note that the Examiner has not indicated on the Office Action Summary sheet whether certified copies of the priority documents have been received in this application. Nor has the Examiner acknowledged Applicants' claim to priority.

Therefore, Applicants respectfully request that the Examiner acknowledge receipt of the priority documents (or request them from the International Office if not yet received) and acknowledge Applicants' claim to priority under 35 U.S.C. §119.

II. Claim Objections

At paragraph 2 of the Office Action, claim 2 is objected to due to an obvious typographical error in the term "additiona".

In response, Applicants include herewith an amendment to claim 2 to delete the term "additiona." In view of the amendment to the claim, Applicants respectfully request reconsideration and withdrawal of this objection.

III. Rejection of Claims Under 35 U.S.C. §112

A. At paragraph 3 of the Office Action, claims 1-10 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner states that while Applicants assert that deposits of the five organisms recited at page 6 of the specification have been made, such an assertion is insufficient assurance that all required deposits have been made and that all the conditions of 37 C.F.R. §§1.801-1.809 have been met.

In response, Applicants include herewith a declaration executed by each of the assignees, stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, and that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on the application.

In view of the declaration, Applicants assert that the claims are fully enabled and therefore respectfully request reconsideration and withdrawal of this rejection.

B. At paragraph 4 of the Office Action, claims 1-10 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner states that the claims are drawn to a vaccine that includes one or more strains of *Eimeria* or antigens of said strains in association with a veterinarily acceptable carrier or excipient. However, the Examiner asserts, protocols and procedures such as for the isolation of antigens, and identification of other strains used in the series of trials, and data obtained when animals were vaccinated/challenged with each of the claimed vaccines are not specifically provided in Applicants' specification. Thus, the Examiner concludes, the metes and bounds of

the invention cannot be ascertained by the information disclosed in the specification, and without proper guidance, the experimentation required to practice the invention would be undue.

In response, Applicants assert that they have fully enabled the vaccine composition of the present invention with respect to the specifically recited *Eimeria* strains that may be included. The specification clearly describes how to isolate the *Eimeria* strains claimed, and how to produce an effective vaccine using these strains. Further, the specific strains have been deposited under the terms of 37 C.F.R. §§1.801-1.809. In addition, as discussed in Example 2 of the specification, various combinations of 2 to 4 of the specifically recited *Eimeria* strains, along with other strains, were made and shown to give “excellent protective against infections with heterologous *Eimeria* strains.” Using this information, together with common knowledge, a person skilled in the art could readily produce a vaccine using any one or more of the novel *Eimeria* strains and determine whether it is effective against disease.

With regard to the identification of other strains that might be used in a vaccine, Applicants include as Appendix A the interim results of a study on the effectiveness of a four-species live coccidiosis vaccine, comprising four strains directly derived from the strains deposited in relation to the present invention. The data obtained with this vaccine in the interim results shows that a protective effect is achieved with each strain present, and that the individual strains do not have any adverse effect on each other in terms of immunity. This evidence confirms that each of the claimed strains is protective, and that any combination of the strains will be useful as a vaccine.

In further support of this position, Applicants include Appendix B which is the summary of further experiments that shows that all species in a vaccine provide protective immunity when administered concurrently (Williams et al., 1997).

Applicants further note that the Examiner has not provided any evidence suggesting that the inclusion of other strains in the vaccine would have any deleterious consequence on the protective effects of the attenuated *Eimeria* strains in the vaccine. Indeed, the Examples of the present application show otherwise. The skilled artisan could readily establish whether the presence of an additional strain would reduce the protective effect of the novel *Eimeria* strains using the experimental data provided in the specification together with the common general knowledge, without undue burden.

As to the Examiner's rejection of the antigens recited in claim 1 as being non-enabled, Applicants assert that the skilled artisan would understand antigens can be readily produced and used in a vaccine formulation in place of whole microorganisms. Once the novel strains of the present invention have been provided, the skilled artisan would be capable of isolating antigens and employing them in a vaccine, using the information provided in the specification together with common general knowledge.

In view of these points, Applicants assert that the pending claims are fully enabled and respectfully request reconsideration and withdrawal of this rejection.

C. At paragraph 5 of the Office Action, claim 2 is rejected as allegedly indefinite because it is unclear to what the term “unattenuate” refers.

In response, Applicants include herewith an amendment to claim 2 wherein the term “unattenuate” has been replaced by the correct tense of the term, namely “unattenuated.” In view of the amendment to the claim, Applicants respectfully request reconsideration and withdrawal of this rejection.

D. At paragraph 6 of the Office Action, claim 8 is rejected as allegedly indefinite because it is unclear to what the term “factured” refers.

In response, Applicants include herewith an amendment to claim 8 wherein the term “factured” has been replaced by the correctly spelled term “fractured.” In view of the amendment to the claim, Applicants respectfully request reconsideration and withdrawal of this rejection.

E. At paragraph 7 of the Office Action, claims 1-10 are rejected as allegedly indefinite because the claims do not spell out the genus and species of the organisms recited therein at their first occurrence.

In response, Applicants include herewith an amendment to claim 1 wherein the full genus and species name of each organism is given upon its first occurrence. In view of the amendment to the claim, Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. Rejection of Claims Under 35 U.S.C. §§102 and 103

A. At paragraph 8 of the Office Action, claims 1-4 and 7-10 are rejected under 35 U.S.C. §102(b) as being anticipated, or under 35 U.S.C. §103(a) as being obvious over, MacDonald et al. (U.S. Patent No. 5,055,292).

The Examiner states that MacDonald et al. teaches a vaccine against coccidiosis in domestic fowls that contains attenuated precocious strains of *Eimeria* species, wherein the species are the same as those recited in the instant application.

In response, Applicants assert that MacDonald et al. does not teach or suggest each element of the rejected claims, and therefore it does not anticipate or make obvious the claimed invention.

Applicants note that as amended, claim 1 recites a vaccine that comprises one or more of the five attenuated *Eimeria* strains prepared by Applicants. Thus, the vaccines of the present invention must contain at least one of the novel *Eimeria* strains prepared by Applicants. In contrast, MacDonald et al. does not teach or suggest any of the five novel strains recited in claim 1 of the present application.

As described in the specification, Applicants prepared a number of different attenuated strains of each species of *Eimeria* used in the present invention by serial passage and by selecting for rapid development. As further stated therein, many of the individual isolates showed poor growth rates, were drug resistant, and/or were unstable. Thus, it is clear that the different isolates of each species were distinct strains with distinct characteristics. Therefore, the skilled artisan working in this field would not expect that the different attenuated isolates of *Eimeria* recited in claim 1 to be the same as the *Eimeria* strains of MacDonald et al.

As the disclosure of MacDonald et al. does not teach or suggest the present invention, MacDonald et al. does not anticipate or make obvious the claimed invention. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. At paragraph 9 of the Office Action, claims 1-10 are rejected under 35 U.S.C. §102(b) as being anticipated, or under 35 U.S.C. §103(a) as being obvious over, Shirley (U.S. Patent No. 4,438,097).

The Examiner states that Shirley teaches a vaccine composition which comprises live attenuated strains of *Eimeria* species, wherein the species are the same as those recited in the instant application.

In response, as with MacDonald et al. discussed above, Applicants note that claim 1 of the present invention recites a vaccine that comprises one or more of the five attenuated *Eimeria* strains prepared by Applicants. Thus, the vaccines of the present invention must contain at least one of the novel *Eimeria* strains prepared by Applicants. There is no evidence that the strains disclosed in Shirley are the same as those of the present invention, nor would the skilled artisan expect that they are the same.

As Shirley does not teach or suggest any of the five novel strains recited in claim 1 of the present application, Shirley does not anticipate or make obvious the claimed invention. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

C. At paragraph 10 of the Office Action, claims 1-10 are rejected under 35 U.S.C. §102(b) as being anticipated, or under 35 U.S.C. §103(a) as being obvious over, Schmatz et al. (WO 94/16725).

The Examiner states that Schmatz et al. teaches live sporulated oocysts that are administered to one day old chickens to provide immunity against coccidiosis, and that this publication teaches vaccines which comprises *Eimeria* species, wherein the species are the same as those recited in the instant application.

In response, as with MacDonald et al. and Shirley discussed above, Applicants note that claim 1 of the present invention recites a vaccine that comprises one or more of the five attenuated *Eimeria* strains prepared by Applicants. Thus, the vaccines of the present invention must contain at least one of the novel *Eimeria* strains prepared by Applicants. There is no evidence that the strains disclosed in Schmatz et al. are the same as those of the present invention, nor would the skilled artisan expect that they are the same.

As Schmatz et al. does not teach or suggest any of the five novel strains recited in claim 1 of the present application, Schmatz et al. does not anticipate or make obvious the claimed invention. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

V. Conclusion

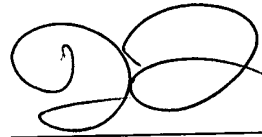
In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. §1.111
U.S. Appln. No. 09/647,098

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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PATENT TRADEMARK OFFICE

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APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims are amended as follows:

1. (Amended) A vaccine comprising which includes ~~(a)~~ one or more components ~~strains selected from the group consisting of~~ *EimeriaE. maxima* ARI-73/97 (deposit no. NM 98/02796), *EimeriaE. acervulina* ARI-77/97 (deposit no. NM 98/02794), *EimeriaE. tenella* ARI-11/98 (deposit no. NM 98/02795), *EimeriaE. necatrix* MCK01 (deposit no. NM 98/02797) and/or *EimeriaE. necatrix* ARI-MEDNEC₃+8 (deposit no. NM 99/02118), an antigen isolated from *Eimeria maxima* ARI-73/97, an antigen isolated from *Eimeria acervulina* ARI-77/97, an antigen isolated from *Eimeria tenella* ARI-11/98, an antigen isolated from *Eimeria necatrix* MCK01, and an antigen isolated from *Eimeria necatrix* ARI-MEDNEC₃+8, and or antigens of said one or more strains, in association with (b) a veterinarily acceptable carrier or excipient.
2. (Amended) ~~The~~A vaccine according to claim 1 which further comprises ~~includes~~ at least one ~~additional~~ unattenuated ~~unattenuate~~ *Eimeria* strain.
3. (Amended) ~~The~~A vaccine according to claim 1 wherein said vaccine comprises ~~which includes~~ *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, and *E. tenella* ARI-11/98, and said vaccine further comprises at least one of ~~one or both of~~ *E. necatrix* MCK01 and *E. necatrix* ARI-MEDNEC₃+8.
4. (Amended) ~~The~~A vaccine according to claim 3 wherein said vaccine further comprises ~~which includes~~ a vaccine strain ~~strains~~ of *EimeriaE. brunetti*, a vaccine strain of *EimeriaE. mitis* and a vaccine strain of *EimeriaE. praecox*.

5. (Amended) ~~The A~~ vaccine according to claim 1 wherein said vaccine further comprises ~~which includes~~ a vaccine against a ~~another~~ poultry disease other than one caused by said components.

6. (Amended) ~~The A~~ vaccine according to claim 5 wherein said vaccine further comprises ~~which includes~~ a vaccine component ~~components~~ effective in providing protection against infection by one or more members selected from the group consisting of Marek's disease, mycoplasma ~~and/or~~ salmonella infection.

7. (Amended) An *Eimeria* strain selected from the group consisting of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and ~~and/or~~ *E. necatrix* ARI-MEDNEC₃+8, ~~or antigens of said one or more strains.~~

8. (Amended) ~~The A~~ vaccine according to claim 1 wherein said vaccine comprises a component ~~strains that is are~~ in the form of a whole and/or fractured ~~factured~~ sporulated oocyst oocysts or sporocysts ~~porocysts~~.

9. (Amended) ~~The A~~ vaccine according to claim ~~8~~ 1 ~~which~~ wherein said vaccine comprises 15 to 500 sporulated oocysts per dose.

10. (Amended) ~~The A~~ *Eimeria* strain according to claim 7 wherein said *Eimeria* strain is in the form of an oocyst or a sporulated oocyst.